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International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61B 1/00

A1

(11) International Publication Number: WO 94/18881

(43) International Publication Date: 1 September 1994 (01.09.94)

(21) International Application Number: PCT/US94/00305

(22) International Filing Date: 10 January 1994 (10.01.94)

(30) Priority Data: 08/023,778 22 February 1993 (22.02.93) US

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(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

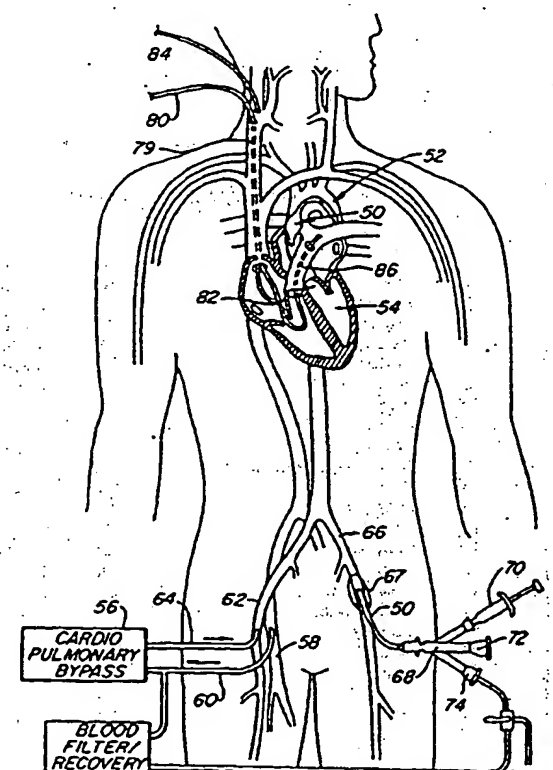
Published

With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: METHOD FOR PERFORMING THORACOSCOPIC CARDIAC BYPASS PROCEDURES

(57) Abstract

A method for closed chest cardiac surgical intervention relies on viewing the cardiac region through a thoracoscope (34) or other viewing scope and endovascularly partitioning the patient's arterial system at a location within the ascending aorta. The cardiopulmonary bypass (56) and cardioplegia can be induced, and a variety of surgical procedures performed on the stopped heart using percutaneously introduced tools. The method of the present invention will be particularly suitable for forming coronary artery bypass grafts, where an arterial blood source is created using least invasive surgical techniques, and the arterial source is connected to a target location within a coronary artery while the patient is under cardiopulmonary bypass and cardioplegia.



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METHOD FOR PERFORMING THORACOSCOPIC CARDIAC BYPASS PROCEDURES

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to thoracoscopic methods for performing cardiac procedures. More particularly, the present invention relates to thoracoscopic methods for performing procedures externally on or internally within the heart while the patient's chest is unopened, the patient's heart is stopped, and the patient is supported by cardiopulmonary bypass.

Coronary artery disease remains the leading cause of morbidity and mortality in Western societies. Coronary artery disease is manifested in a number of ways. For example, disease of the coronary arteries can lead to insufficient blood flow resulting in the discomfort and risks of angina and ischemia. In severe cases, acute blockage of coronary blood flow can result in myocardial infarction, leading to immediate death or damage to the myocardial tissue.

A number of approaches have been developed for treating coronary artery disease. In less severe cases, it is often sufficient to treat the symptoms with pharmaceuticals and lifestyle modification to lessen the underlying causes of disease. In more severe cases, the coronary blockage(s) can often be treated endovascularly using techniques such as balloon angioplasty, atherectomy, laser ablation, stents, hot tip probes, and the like.

In cases where pharmaceutical treatment and/or endovascular approaches have failed or are likely to fail, it is often necessary to perform a coronary artery bypass graft procedure using open surgical techniques. Such techniques require that the patient's sternum be opened and the chest be spread apart to provide access to

includes a distal balloon which can be expanded to occlude the ascending aorta. The coronary ostia remain unblocked so that the heart and proximal ascending aorta may be isolated while the patient is on cardiopulmonary bypass. This catheter is particularly intended to be used in heart valve replacement procedures.

SUMMARY OF THE INVENTION

According to the present invention, a method for closed-chest cardiac surgical intervention relies on viewing the region of the heart through a percutaneously positioned viewing scope, such as a thoracoscope. The patient's arterial system will be partitioned during such interventional procedures at a location within the ascending aorta between the brachiocephalic artery and the coronary ostia. In a preferred embodiment, such partitioning is achieved by endovascularly advancing the distal end of a catheter to the desired location with the ascending aorta and expanding a blocking element on the catheter at said location to inhibit the flow of blood and other fluids past said location. Such partitioning facilitates isolation of the heart, and in particular permits the heart to be stopped while the patient is supported by cardiopulmonary bypass. Once the patient's heart is stopped, a variety of surgical procedures can be performed using percutaneously introduced instruments in a minimally invasive fashion.

The methods of the present invention will be particularly useful for forming coronary artery bypass grafts in a patient suffering from coronary artery disease. The methods will be performed while the treating physician views the region of the heart through the viewing scope, with initial portions of the procedures being performed while normal heart function is maintained. As a first step, the physician will prepare an arterial blood source, typically by harvesting an internal mammary artery or other suitable artery. Conveniently, the lung beneath the internal mammary

Fig. 2 is a cross-sectional view illustrating the placement of a single trocar sheath between adjacent ribs according to the present invention.

Fig. 3 illustrates the use of an electrosurgical tool introduced through a trocar sheath in order to dissect the left internal mammary artery from the inner thoracic wall to free the artery prior to transection.

Fig. 4 illustrates the use of a clip applier introduced through a trocar sheath in order to seal off portions of the left internal mammary artery prior to transection.

Fig. 5 illustrates transection of the left internal mammary artery to provide an arterial blood source according to the method of the present invention.

Fig. 6 illustrates the use of an endovascular catheter to partition the patient's heart at a location within the ascending aorta according to the method of the present invention. Fig. 6 further illustrates the connection of a cardiopulmonary bypass system to the patient, as well as the optional placement of a retrograde cardioplegia catheter.

Fig. 7 illustrates the preparation of the heart prior to formation of an arteriotomy in the left anterior descending coronary artery which acts as a target location for connection of the internal mammary artery.

Figs. 8-13 illustrate the steps of preparing the coronary artery and suturing the internal mammary artery to an incision formed in the coronary artery in order to complete the desired coronary bypass graft. These steps are performed in the region of the coronary artery detailed as circle 8-8 in Fig. 7.

Fig. 14 shows the heart after completion of the coronary artery bypass procedure of the present invention, particularly illustrating the bypass from the left internal mammary artery to the distal left anterior descending coronary artery.

inserted for selective ventilation or deflation of either lung.

After the patient has been prepared as described above, a plurality of access trocar sheaths 10, 12, 14, and 16 will be positioned in the lateral chest of the patient P, as illustrated in Fig. 1. The trocar sheaths of Fig. 1 are shown on the left side of the patient and will be used in the creation of an anastomosis between the patient's left internal mammary artery and the left anterior descending coronary artery, as will be described in detail hereinafter. Note that it will frequently be desirable to have one or more access trocar sheaths in position on the right side of the patient, particularly to permit the introduction of grasping tools to facilitate repositioning the heart, as described in more detail hereinafter. In addition, it may be desirable to position one or more trocar sheaths in parasternal location(s) as well. Usually, one trocar sheath, for example, trocar sheath 12, will be positioned first, and a thoracoscope will be introduced therethrough. The remaining trocar sheaths 10, 14, and 16 can then be positioned based on the relative positions of the coronary arteries and other internal body structures which can be viewed after the thoracoscope has been initially placed.

The trocar sheaths 10, 12, 14, and 16 used in the methods of the present invention will generally be shorter than those used for conventional laparoscopic procedures. Typically, trocar sheaths useful for the present invention will have a length in the range from about two to 10 cm, and an internal diameter in the range from two to 15 mm. In addition, the trocar sheaths can be flexible to permit manipulation of tools introduced therethrough. As illustrated in Fig. 2, the trocar sheaths will generally be introduced between adjacent ribs R and will penetrate with their caudal aspect lying just above the superior rib surfaces. Suitable

provide the arterial blood supply) and at the other end to the target location on the coronary artery.

The left internal mammary artery is suitable as an arterial source for target locations on the left anterior descending coronary artery, the diagonal coronary artery, the circumflex artery/obtuse marginal artery, and the ramus intermedius coronary artery. The right internal mammary artery is available for connection to all of the same target locations, as well as the right coronary artery and the posterior descending artery. The gastroepiploic artery and free grafts from the aorta will be available for all target locations.

Referring now to Figs. 3 and 4, an exemplary procedure according to the present invention for transecting the left internal mammary artery IMA will be described. Initially, the left lung is deflated and an electrosurgical tool 30 is used to dissect a length of the internal mammary artery IMA from the inner thoracic wall. The side branches of the internal mammary artery are sealed. The electrosurgical tool 30 is then introduced through trocar sheath 12 while a grasper 32 or other tool for applying tension on the artery IMA is introduced through trocar sheath 14. The thoracoscope 34 may be positioned through the trocar sheath 16 in order to most advantageously view the operating area at this point in the procedure.

After the internal mammary artery IMA is freed from the thoracic wall, the electrosurgical tool 30 will be replaced with a clip applier 36, with the thoracoscope 34 being moved to trocar sheath 14 and the graspers 32 being moved to trocar sheath 10. The clip applier 36 (Fig. 4) is then used to place one clip 40 upstream and a second clip 42 downstream of a region of the internal mammary artery IMA to be transected, as illustrated in Fig. 5. Upstream clip 40 will be a temporary occlusion device (e.g., a Fogarty clip, Baxter Corp.) which is later removed from the internal mammary artery IMA to

solution that contains a high concentration of cardioplegic chemicals.

Referring to Fig. 6, the arterial system may be partitioned using an aortic occlusion balloon catheter 50 which is positioned in the ascending aorta 52 to separate the left ventricle 54 and proximal portion of the ascending aorta from the rest of the patient's arterial system. A cardiopulmonary bypass system 56 removes venous blood from the femoral vein 58 using a conventional blood withdrawal catheter 60. The bypass system 56 removes carbon dioxide from the blood, oxygenates the blood, and returns the oxygenated blood to the patient's femoral artery 62 through a conventional return catheter 64. The bypass system 56 will operate at a sufficient pressure to drive the circulation of the blood through the patient's arterial system except for that portion which is blocked by the aortic occlusion catheter.

The aortic occlusion catheter 50 is preferably endovascularly introduced over a conventional guidewire to the ascending aorta through the left femoral artery 66 which is entered either percutaneously or through an open cut down 67 of the groin. A proximal hub 68 is located on the proximal end of the occlusion catheter 50 and includes a balloon inflation means, such as syringe 70, a main access port 72 to permit the introduction of instruments, irrigation fluid, and the like. Optionally, a third introduction port 74 may be provided to recirculate a portion of the venous blood from catheter 60. The provision of access ports in the aortic occlusion catheter 50 is optional. It is necessary only that the catheter 50 be able to position a blocking element, such as the inflatable balloon, at the proper location within the ascending aorta. One or more access ports and lumens, however, may be an advantage in a variety of circumstances. For example, the catheter 50 with an access lumen would permit anterograde

In addition to provisions for cardiopulmonary bypass and for arterial system partition, the patient will be prepared to receive the introduction of a fluid containing cardioplegic agents to the myocardium. Such agents may be delivered directly into the aortic root and coronary ostia in an anterograde manner employing the aortic occlusion catheter for such delivery. The blocking element of the aortic occlusion catheter prevents escape of cardioplegic fluid into the remainder of the arterial circulation.

Alternatively, the cardioplegic agents can be delivered in a retrograde fashion using a coronary sinus catheter 80 which is introduced in a conventional manner through the patient's right internal jugular vein 79, and includes a balloon at the distal end of the catheter extending into the coronary sinus 82. A pulmonary artery venting catheter 84 may also be introduced through the right internal jugular vein 79 and eventually into the pulmonary trunk 86, as illustrated. The pulmonary venting catheter 84 may include an inflatable balloon (not illustrated) which can be used if necessary to occlude the pulmonary trunk 86 as well as an inner lumen which can vent fluid from the pulmonary trunk and thereby decompress the left ventricle 54 as necessary during the procedure. Use of the aortic occlusion catheter 50, the coronary sinus catheter 80, and the pulmonary venting catheter 84 is described more fully in copending application serial number 07/730,559, the disclosure of which has previously been incorporated herein by reference.

Cardiopulmonary bypass and cardioplegia are then initiated as follows. First, the cardiopulmonary bypass system 56 is activated, followed by inflation of the blocking balloon on the aortic occlusion catheter. The blocking balloon will be positioned between the brachiocephalic artery and the coronary ostia, neither of which will be occluded. In this way, the patient's left

electrically inducing fibrillation. The necessary electrodes could be introduced through selected trocar sheaths, or could be applied externally on the patient's chest. See, Aikins (1984) J. Thorac. Cardiovasc. Surg. 88:174, for a description of such techniques. Use of chemical cardioplegia to arrest the heart will generally be preferred, since the cooled, arrested heart will have a much lower oxygen requirement than the fibrillating heart, which reduces the likelihood of intraoperative injury to the heart.

The patient is now ready to have the diseased coronary artery or arteries prepared for anastomoses. Initially, a pericardiotomy is performed to provide access to the coronary arteries. The pericardiotomy can be performed using suitable instruments, such as electrosurgical instruments, introduced through the lateral chest trocar sheaths (Fig. 1) while viewing the region through the thoracoscope. The pericardium can be incised and spread open for access, or portions of the pericardium can be excised and removed from the thoracic cavity.

Referring now to Fig. 7, the decompressed heart H will now be repositioned using suitable instruments in order to better expose the coronary artery which is the target for anastomosis. Suitable tools include hooks, suction catheters, grasping rods, pushing rods, and the like. Gravity can also be used to help position the heart if the patient can be turned appropriately. As illustrated in Fig. 7, a pair of graspers 90 may be used to secure opposite sides of the heart and permit turning of the heart as desired. Optionally, additional trocar sheaths may be introduced at other sites of thoracic access. For example, one or more parasternal punctures, one or more punctures in the midclavicular line, and/or a subxyphoid puncture may be introduced.

As illustrated, the left anterior descending coronary artery LAD is first pulled upward from the

to return to its natural orientation. The aortic occlusion catheter 50 will be deflated. Both lungs will be ventilated, and the coronary arteries will be perfused with blood to initiate cardiac contractions in a conventional manner. If necessary, the heart will be defibrillated to correct its rhythm using electrodes placed either on the heart surface via trocar sheaths or on the patient's body surface. The cardiopulmonary bypass will be gradually reduced and stopped. The aortic occlusion catheter will be removed, and the bypass catheters withdrawn. The groin penetrations will be repaired as necessary, all remaining trocar sheaths will be removed, and all thoracic punctures will be sealed in a conventional manner. Finally, the patient will be recovered from anesthesia.

Although the foregoing invention has been described in some detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that certain changes and modifications may be practiced within the scope of the appended claims.

6. A method for forming a coronary artery bypass graft in a patient, said method comprising:

forming at least one percutaneous penetration in the patient's chest;

viewing the region of the heart through a viewing scope disposed through a percutaneous penetration;

forming an arterial blood source;

endovascularly partitioning the patient's arterial system at a location within the ascending aorta between the brachiocephalic artery and the coronary ostia;

establishing cardiopulmonary bypass;

stopping heart contraction; and

connecting the arterial blood source to a location in a coronary artery downstream from an occlusion using tools introduced through a percutaneous penetration while viewing the region of the stopped heart through the viewing scope.

7. A method as in claim 6, wherein the viewing scope is introduced through a trocar sheath disposed in a percutaneous penetration.

8. A method as in claim 6, wherein the arterial blood source is formed by transecting an artery.

9. A method as in claim 8, wherein the transected artery is a mammary artery.

10. A method as in claim 6, wherein the arterial blood source is formed by grafting a natural or synthetic blood vessel to the aorta.

11. A method as in claim 6, wherein the arterial system is partitioned by endovascularly advancing a distal end of a catheter to the location

while viewing the artery using the viewing scope while the heart is stopped; and

connecting the transected internal mammary artery to the incision in the coronary artery using a tool introduced through one of the trocar sheaths while viewing the arteries using the viewing scope while the heart is stopped.

16. A method as in claim 15, wherein at least three trocar sheaths are positioned on the lateral chest and between adjacent ribs.

17. A method as in claim 15, wherein the internal mammary artery is transected using an electrosurgical cutting tool to dissect the artery from the thoracic wall and a cutting tool to sever the proper length of the artery.

18. A method as in claim 15, wherein the arterial system is partitioned by endovascularly advancing a distal end of a catheter to the location within the ascending aorta, and expanding a blocking element on the catheter at said location to inhibit the flow of blood and other fluids past said location.

19. A method as in claim 15, wherein cardiopulmonary bypass is established from the femoral vein to the femoral artery.

20. A method as in claim 18, wherein the heart is stopped by the anterograde introduction of cardioplegic fluid through the catheter.

21. A method as in claim 15, wherein the incision in the coronary artery is formed using a scalpel.

arterial system downstream from the occluded ascending aorta;

means for inducing cardioplegia; and

surgical tools for operating on and around the external surface of the heart.

28. The system of claim 27, wherein the means to occlude the ascending aorta is an elongated aortic catheter having proximal and distal ends and an expandable member on a distal portion thereof, the catheter being adapted to be advanced through the patient's aorta until the expandable member on the distal portion is disposed at a location between the ostia of the coronary arteries and the brachiocephalic artery and the expandable member being shaped and dimensioned so that, upon the expansion thereof within the patient's ascending aorta, the aortic passageway therethrough is occluded.

29. The system of claim 27, wherein the means to occlude the ascending aorta includes a clamp adapted to be applied to the exterior of the ascending aorta at a location between the coronary arteries and the brachiocephalic artery.

30. The system of claim 27, wherein the cardiopulmonary bypass system includes means to withdraw blood from the patient's venous system, means to remove carbon dioxide from the withdrawn blood, and means to oxygenate the withdrawn blood which is directed into the patient's arterial system downstream of the occluded ascending aorta.

31. The system of claim 27, further comprising a plurality of trocar sheaths which can be disposed within a relatively small opening in the patient's chest

introducing cardioplegic material into at least one of the patient's coronary blood vessels.

34. The system of claim 32, further comprising a plurality of trocar sheaths which can be disposed within the relatively small openings in the patient's chest to define an introducing path for the viewing scope and surgical tools.

35. A system as in claim 30, further comprising a coronary sinus catheter which permits retrograde delivery of cardioplegic fluid to the heart.

36. A system as in claim 30, further comprising a pulmonary venting catheter which can vent fluid from the pulmonary trunk and decompress the left ventricle.

37. A system as in claim 30, further comprising an aortic root vent catheter which may be introduced through the aortic occlusion catheter to vent the left ventricle.

38. A system for performing a coronary artery bypass graft procedure in a patient including:

an aortic occlusion catheter;

a first cutting tool which can be inserted into the patient's chest cavity through a small opening in the patient's chest to create an arterial blood source within the patient's chest cavity by severing an artery and providing a free, upstream end of the artery within the chest cavity under observation through a percutaneously introduced viewing scope;

a second cutting tool which can be inserted into the patient's chest cavity through a small opening in the patient's chest to form an incision in a coronary artery downstream from a blockage therein under

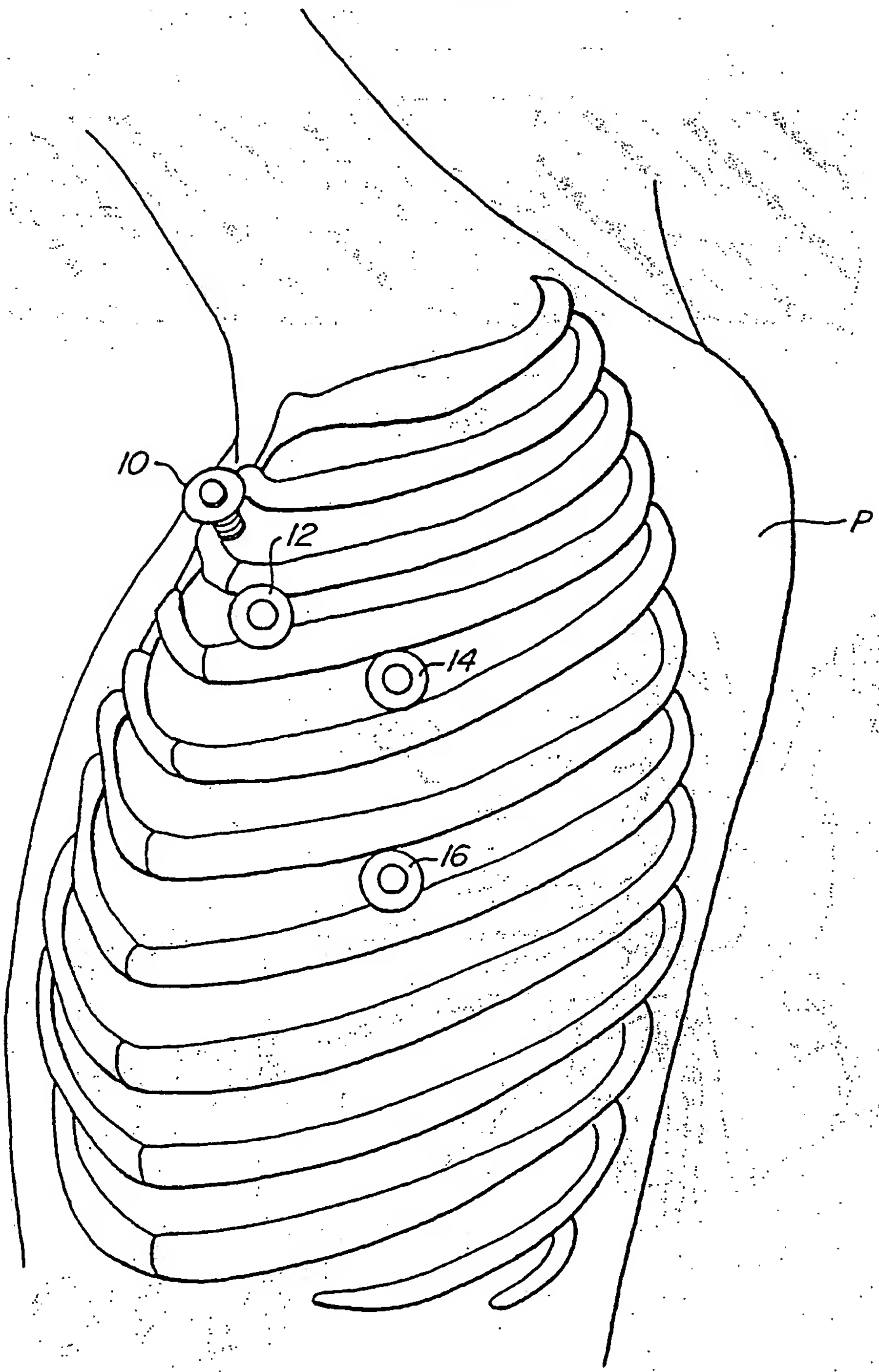


FIG. 1.

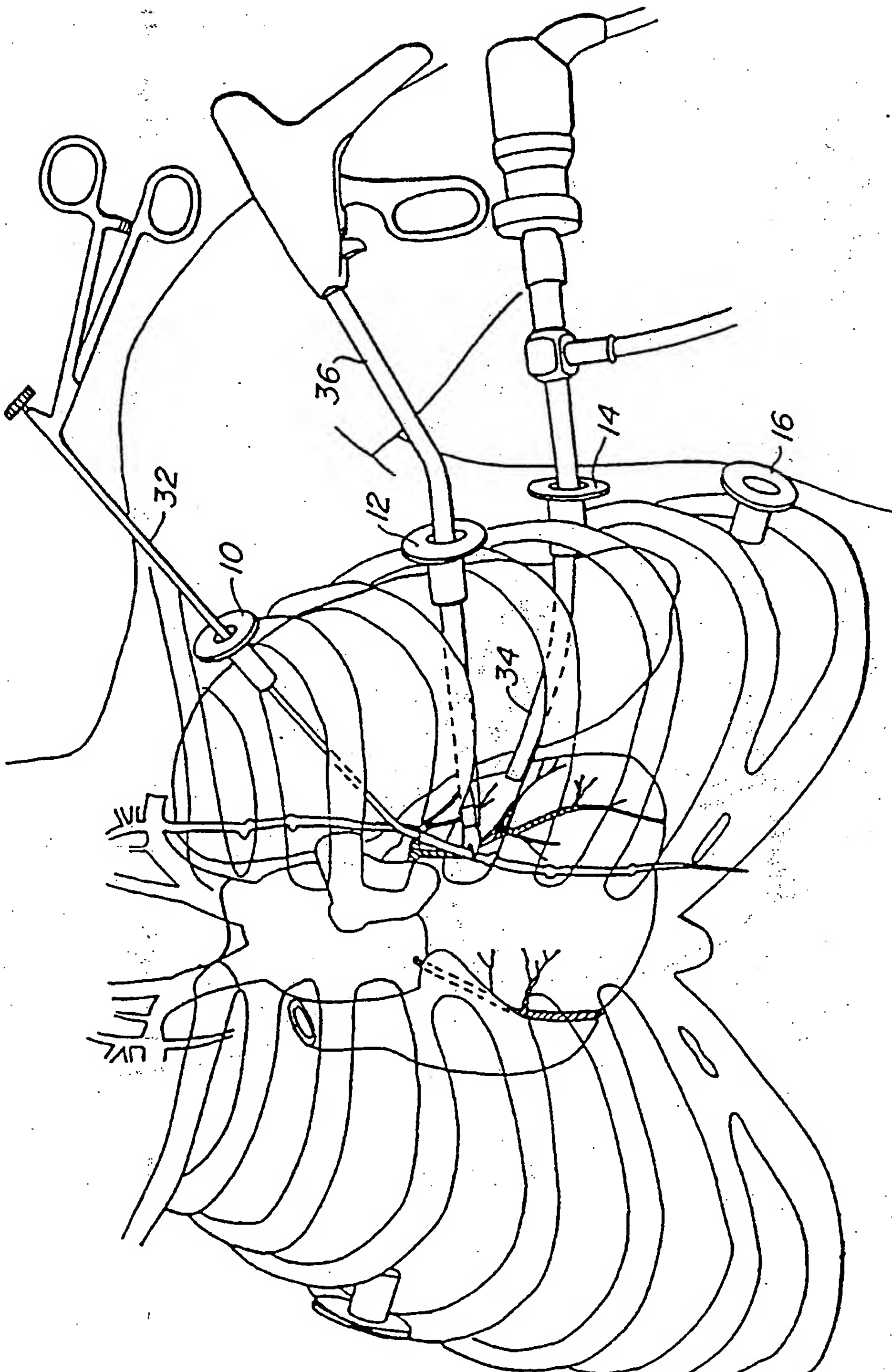
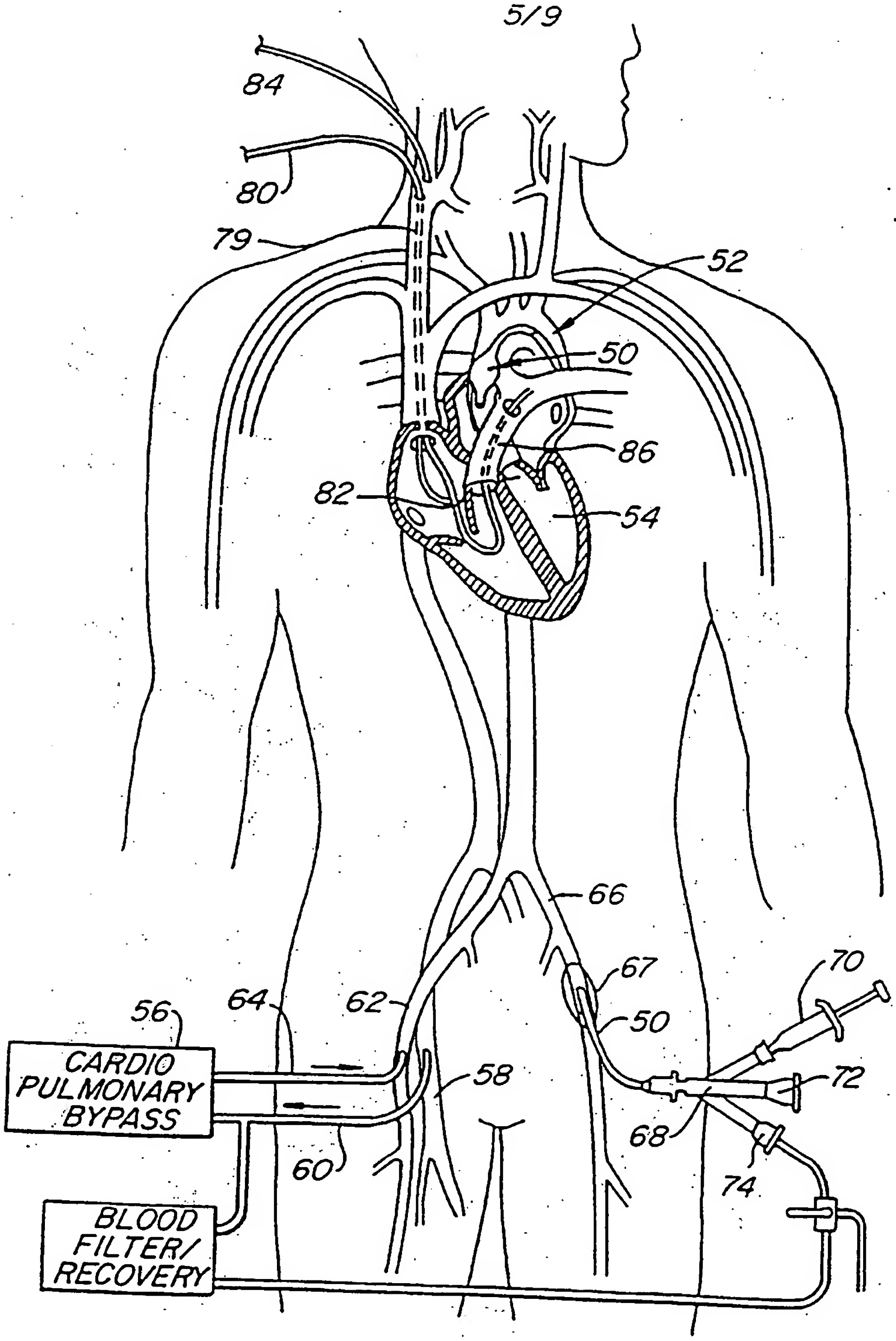


FIG. 4.



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CARDIO PULMONARY BYPASS
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BLOOD FILTER/ RECOVERY

FIG. 6.

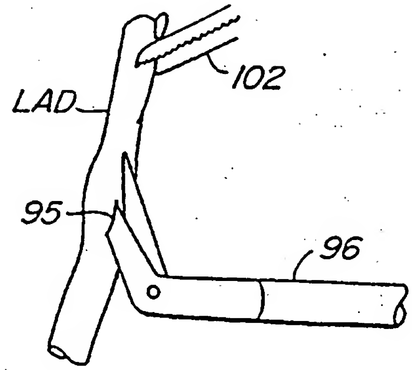

FIG. 8.

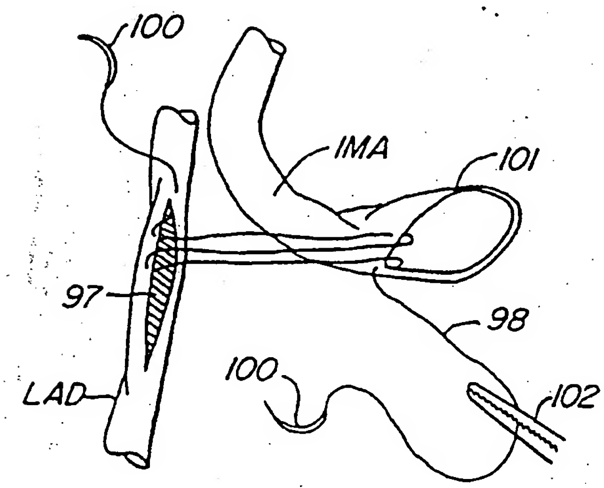

FIG. 9.

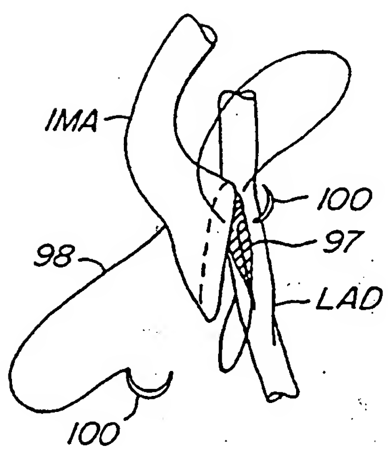

FIG. 10.

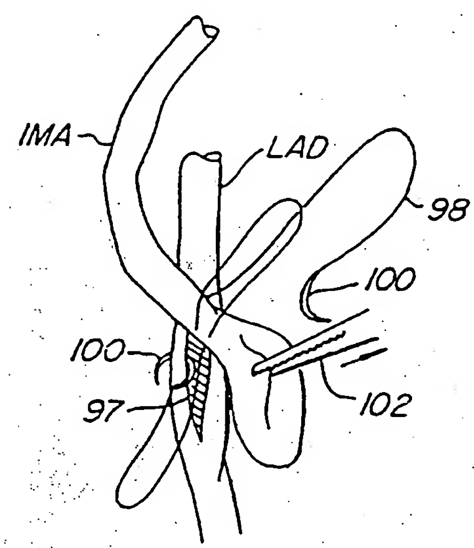

FIG. 11.

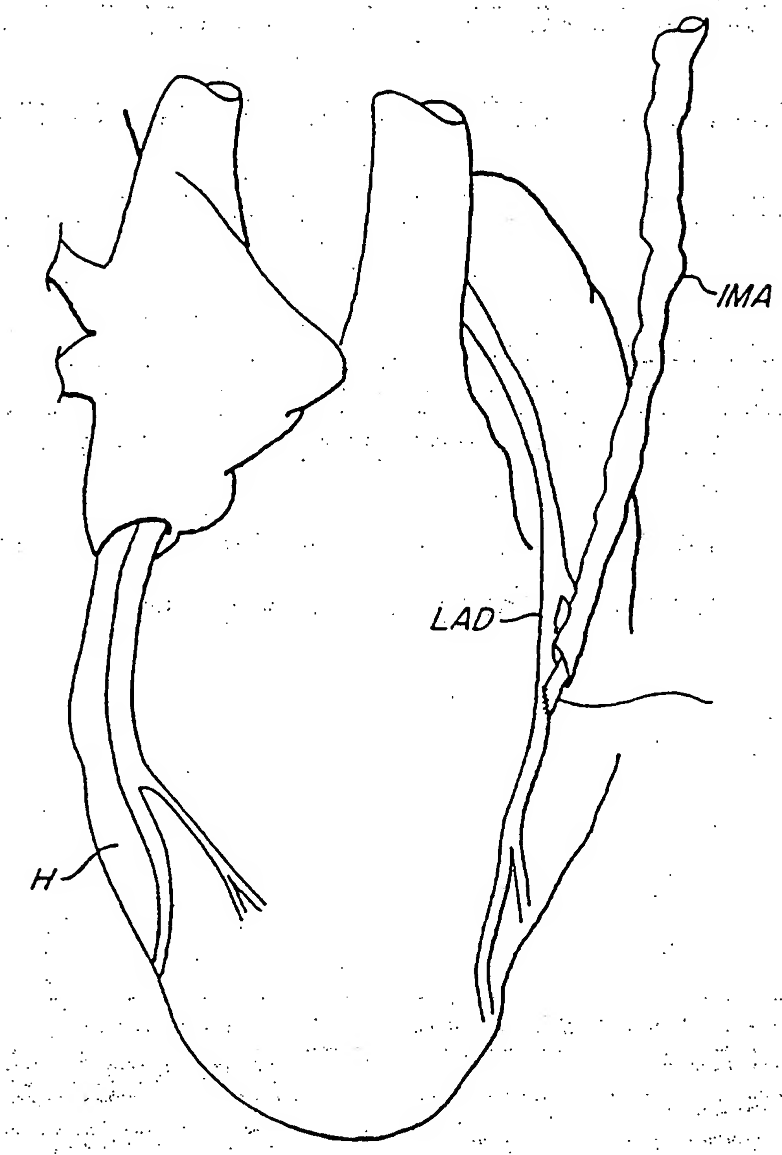

FIG. 14.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/00305

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-5

Remark on Protest
☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.